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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Miles B. Brennan *et al.*

Serial No: 09/458,579

Examiner: Seharaseyon, Jegatheesan

Filed: December 9, 1999

Group Art Unit: 1647

For: Methods of Identifying Compounds  
Useful for the Regulation of Body  
Weight and Associated Conditions

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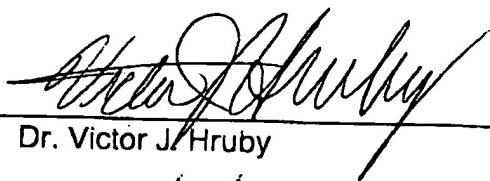
DECLARATION PURSUANT TO 37 CFR 1.132

I, Victor J. Hruby, declare as follows:

1. I obtained my Ph.D. in Chemistry in 1965 from Cornell University, Ithaca, N.Y.
2. Much of my research has been directed to developing a better understanding of peptide hormone and neurotransmitter chemistry, synthesis, biology, and biophysics. During the course of my research, I have investigated the structure-activity relationships of novel, melanotropin peptides and peptidomimetics with agonist and antagonist activities at the melanocortin receptors.

3. I am not being paid for this opinion.
4. I have reviewed and understand U.S. Patent Application Serial Number 09/458,579, entitled "Methods of Identifying Compounds Useful for the Regulation of Body Weight and Associated Conditions" ("the application").
5. This application relates to the field of endocrinology. I am a person of skill in the art in this field.
6. Having read the application, I believe that the application teaches, in part, methods for identifying compounds that regulate the peripheral melanocortinergic pathway of energy homeostasis.
7. I believe that the application teaches that such methods include selecting compounds that preferentially bind to and/or activate peripheral melanocortin receptors.
8. I understand that the application teaches the use of peripheral melanocortin receptors to stimulate lipolysis and/ or to inhibit fatty acid uptake by adipocytes.
9. At the time this application was filed, December 9, 1999, those practicing in this field believed that MC1-R, MC2-R, MC3-R, MC4-R, and MC5-R were found in the periphery.
10. At the time this application was filed, December 9, 1999, I, as well as others practicing in this field, considered that proopiomelanocortin (POMC) compounds were involved in the central pathways of energy homeostasis.
11. Having read the application, I believe it teaches the importance of the *peripheral* melanocortinergic pathway in maintaining energy homeostasis via the action of POMC compounds on peripheral melanocortin receptors.
12. I as well as others practicing in this field now recognize the importance of the peripheral melanocortinergic pathway of energy homeostasis.
13. I declare that all statements made of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that

these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above applications or any patent granted therein.



Dr. Victor J. Hruby

11/18/03

Date